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Denying May Yet Make Sense

Timaran and others¹ report on what essentially appears to be a registry-based observational study and go at length to explain why their results may be used to refute the results of the EVAR (endovascular aortic aneurysm repair) 2 trial.² They recognize the fact that by definition their design is inferior but still claim that no patients should be denied “rescue” by a vascular surgeon. Interestingly, framing the message as denying care instead of what more appropriately may be called offering optimal medical care already sets the scene.

However, the pivotal problem that can never be resolved, even if the study represented the experience of the entire world, is what would have happened had these patients not been offered EVAR. The latter notion seems beyond the authors’ conception. The fact is that the authors simply do not provide a satisfactory explanation for the huge difference in complication rates between their series and the EVAR 2 trial. This makes interpretation extremely difficult, and therefore this study cannot provide a proper basis for a considered health care policy decision.

Finally, and not least important, is the fact that the authors completely neglect the issue of competing morbidity and mortality in this high-risk population. It would appear that if the EVAR 1 and DREAM trials showed equal overall survival 1 year after randomization simply because of increased cardiovascular mortality in EVAR survivors, the margin for a relevant survival benefit would be extremely small if existent at all.^{3,4} Have the authors even considered the possibility that not denial of care but optimal medical care may be the best option for this frail population, also from a health economic perspective?

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In reply

We appreciate Dr Buskens’ discerning comments and questions. Although our study was indeed an observational registry-based study, it is likely the largest cohort of its kind and represents the early outcomes of the vast majority of EVARs performed

in the United States over the last 5 years.¹ Most other studies compare smaller populations, are restricted to major academic centers, and have highly selected patients and operators.^{2,5} Our findings, however, confirm those of other large observational studies, which have clearly established that the high 30-day and in-hospital mortality reported in the EVAR trial 2 is not seen in the United States, even in the highest-risk patients or those unfit for open repair.^{2,3} Although no randomized trial, except for EVAR 2, has assessed the perioperative outcomes of EVAR among the highest-risk patients, the immediate need of data that could justify its use warranted additional investigation in the United States to define health care policy. In this regard, we do agree with Dr Buskens that the proper basis for health care policy definition needs to include the results of several studies that reflect the outcomes and current practices in a particular country. Our study, in conjunction with others, has clearly proven that the perioperative mortality of EVAR in the United States is low, even in the highest-risk patients. Our conclusion, ie, that EVAR should not be denied to high-risk patients with abdominal aortic aneurysm in the United States on the basis of the level 1 evidence from the British study, is therefore supported by others.^{2,3}

Dr Buskens claims that we have neglected the issue of morbidity and mortality of the highest-risk patients undergoing EVAR and have not considered the importance of optimal medical therapy to improve outcomes. Although our study focused on perioperative in-hospital mortality, other observational studies have confirmed that EVAR can result in improved long-term survival in all risk categories, including patients unfit for open repair.^{2,3} Obviously, improved perioperative outcomes and patient survival do not result only from an optimal surgical or interventional procedure, but also from offering the best medical management. In this regard, we do believe that refinements and effectiveness in assessing and improving “fitness” with treatment of comorbidities, provider experience, and lack of treatment delays may account for the improved outcomes in the United States as compared with those reported in the EVAR 2 trial. As vascular specialists, we do not “neglect” best medical management. Quite the opposite: we incorporate it in the management of all patients undergoing vascular procedures.

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